PSJ3

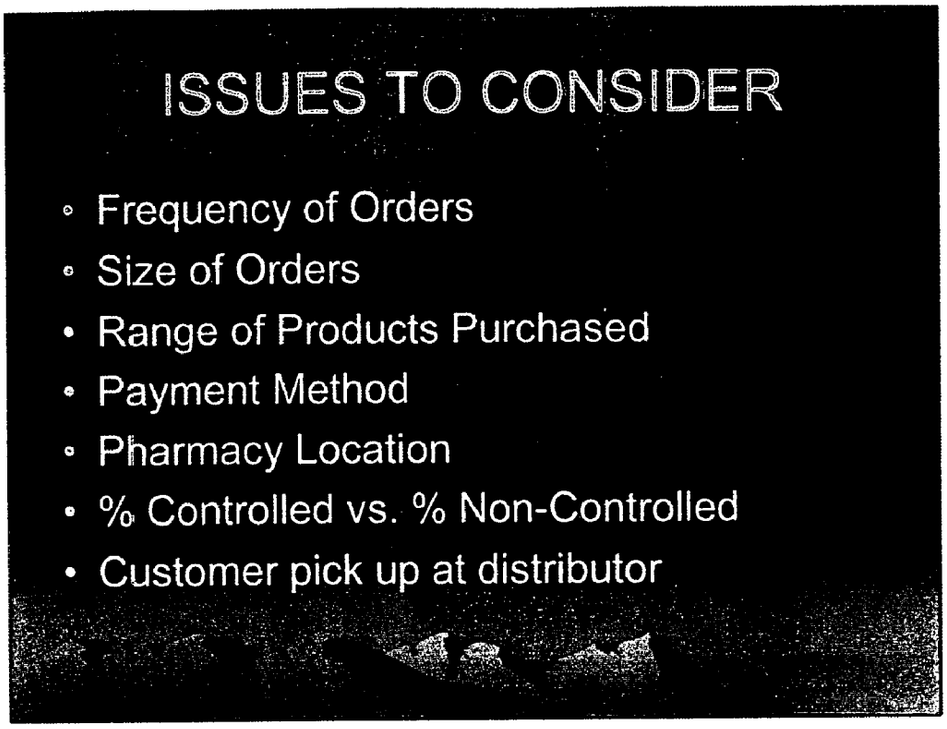
Exhibit 210A

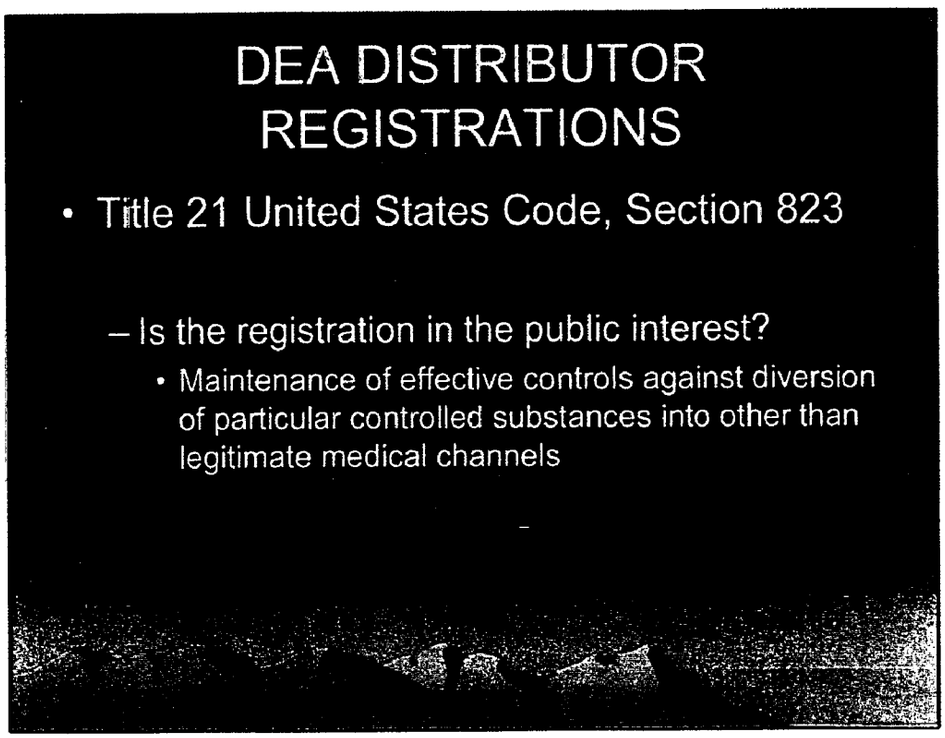
INTERNET PHARMACY DATA

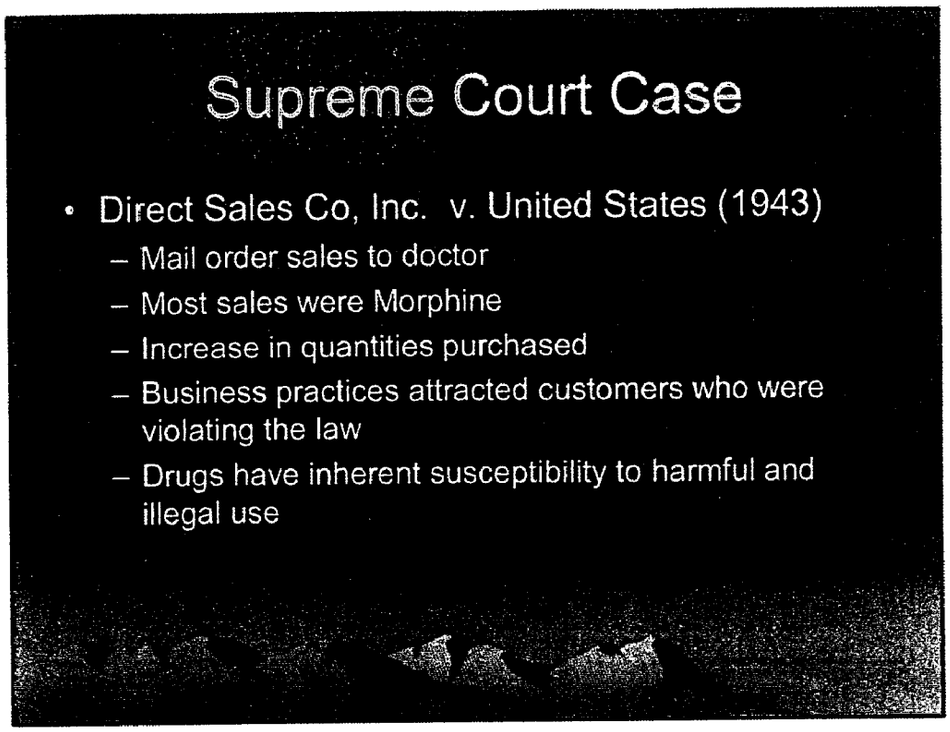
Meeting With
AmerisourceBergen
DEA Headquarters
August 10, 2005

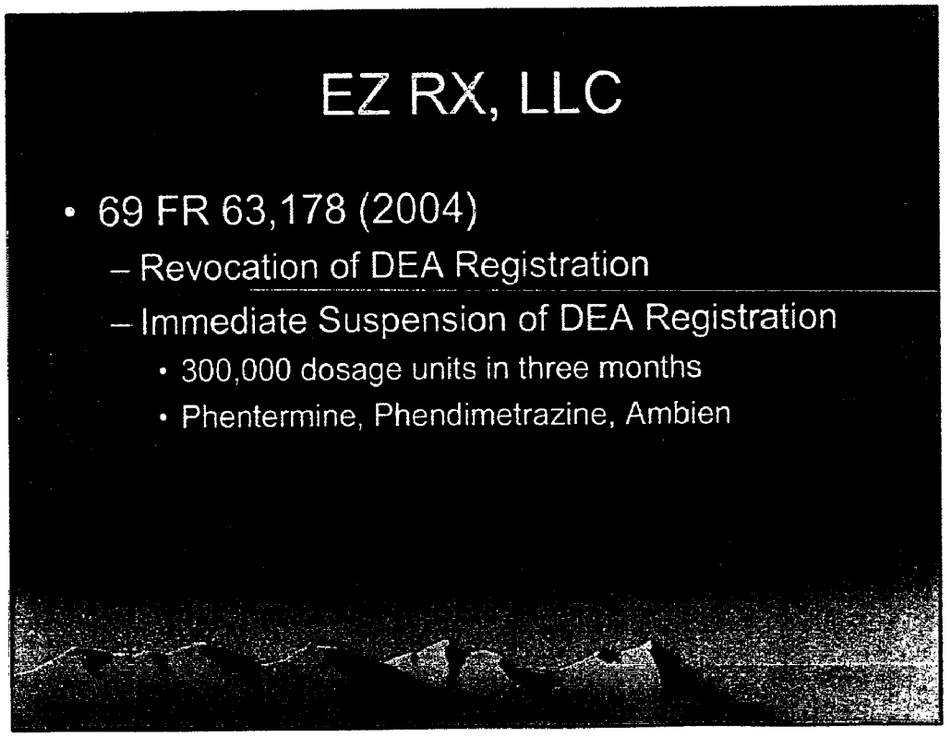
Internet Pharmacies

- Domestic Based
  - Related to an existing pharmacy
    - Walk in patients with prescriptions
    - Some legitimate some not
  - Unrelated to brick and motor pharmacy
    - No local patients or doctors
    - No walk-in business
- Foreign based









RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
  - Revocation of DEA Registration
  - Immediate Suspension of DEA Registration
    - 19,300,000 dosage units of various controlled substances
    - Based on Internet Questionnaires
  - Not in the course of professional practice

Supreme Court Case

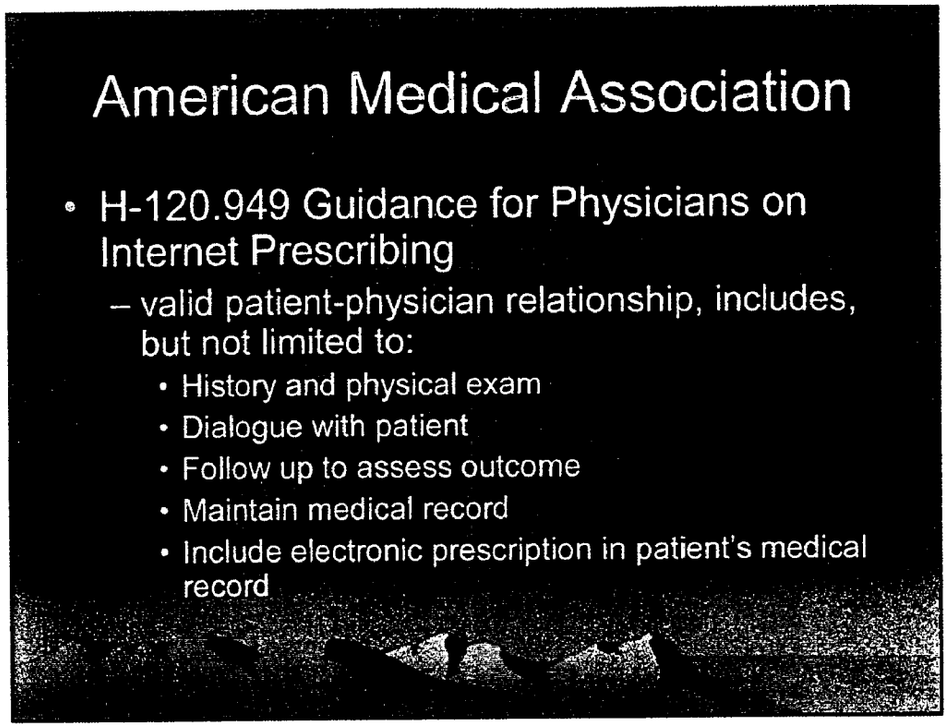
- United States v. Moore
  423 U.S. 122 (1975)
  - Usual course of professional practice
    - Patient with a Medical Complaint
    - History
    - Physical Examination
    - Nexus Between Complaint/History/Exam and Drug Prescribed

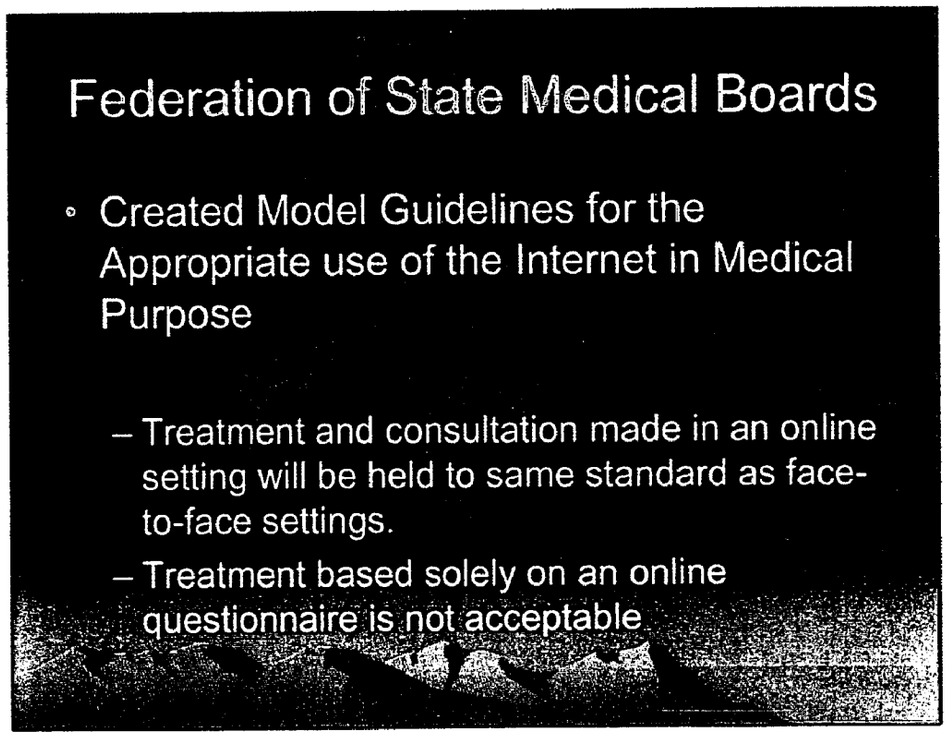
DEA Internet Policy

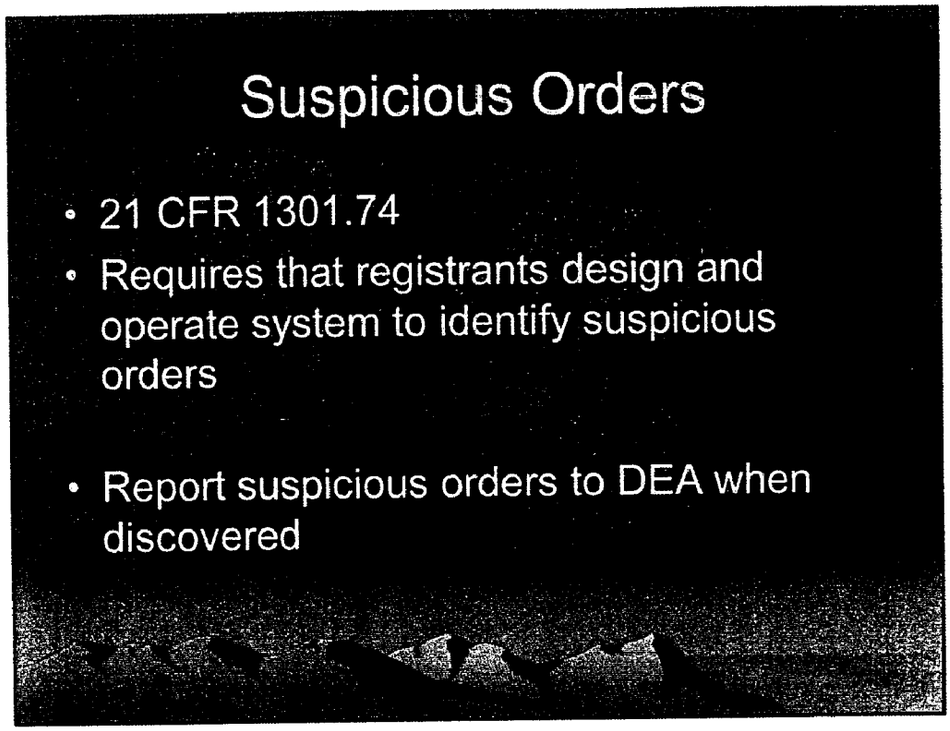
- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

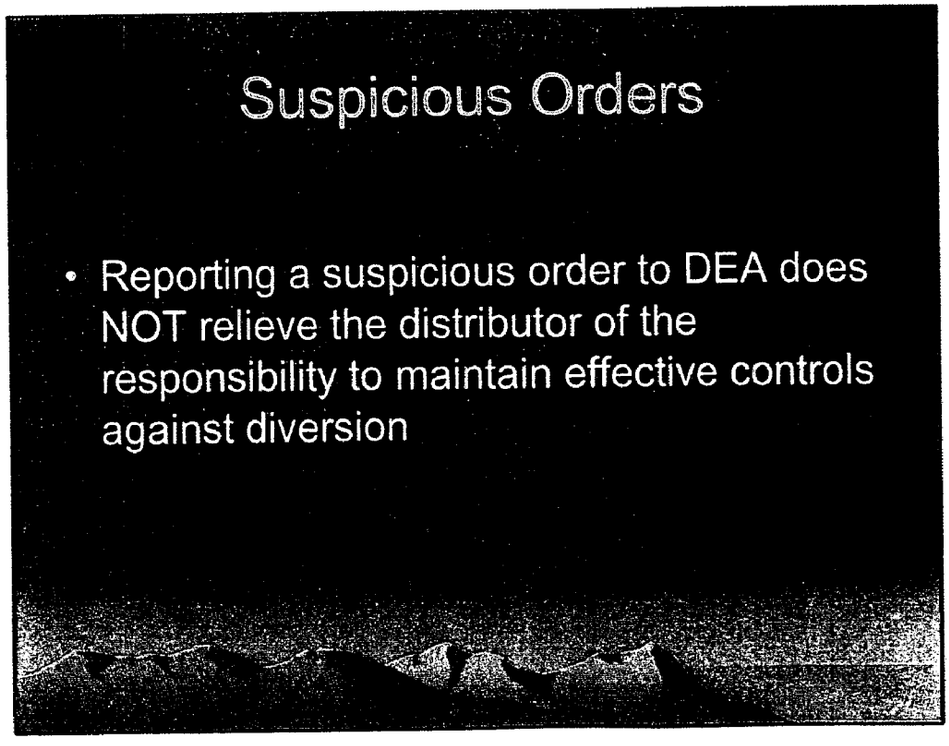
VERIFIED INTERNET PHARMACY PRACTICE SITES (VIPPS)

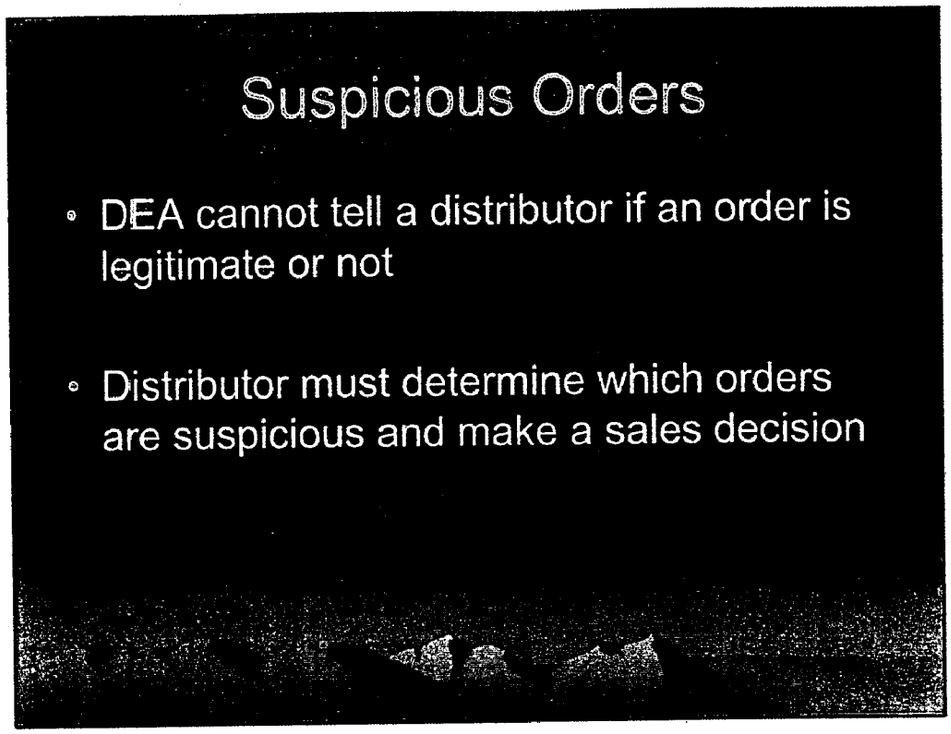
- National Association of Boards of Pharmacy
  - Licensed, legitimate, Inspection
  - 14 VIPPS Approved Pharmacies as of 06-27-2005
  - www.nabp.net/vipps/consumer/faq.asp

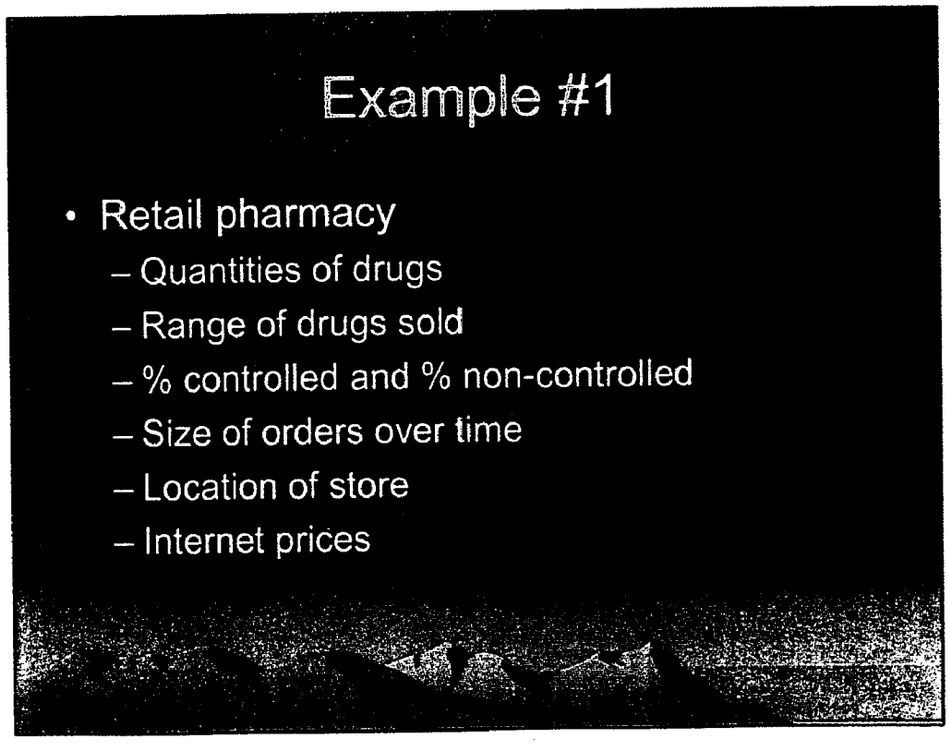




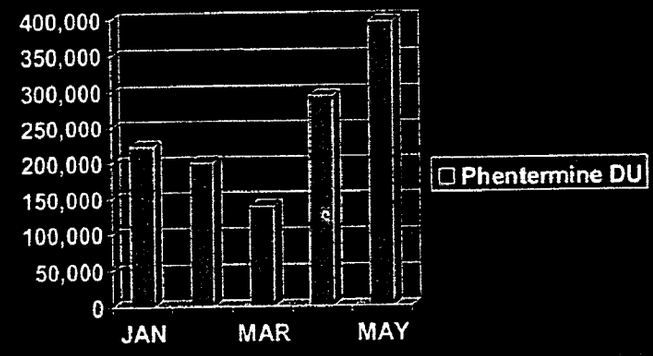






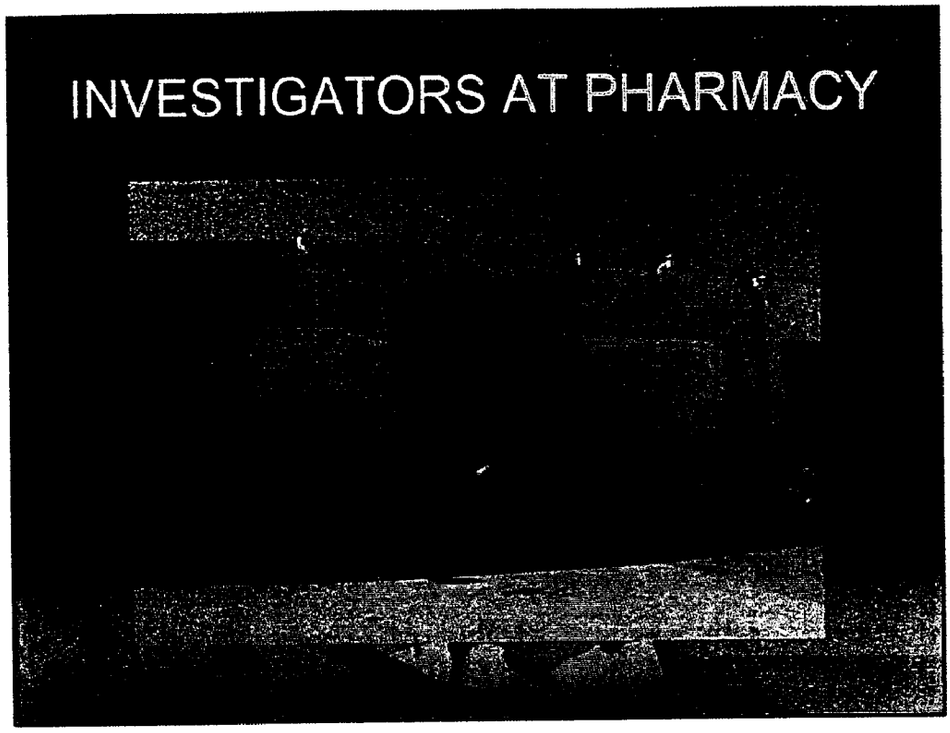


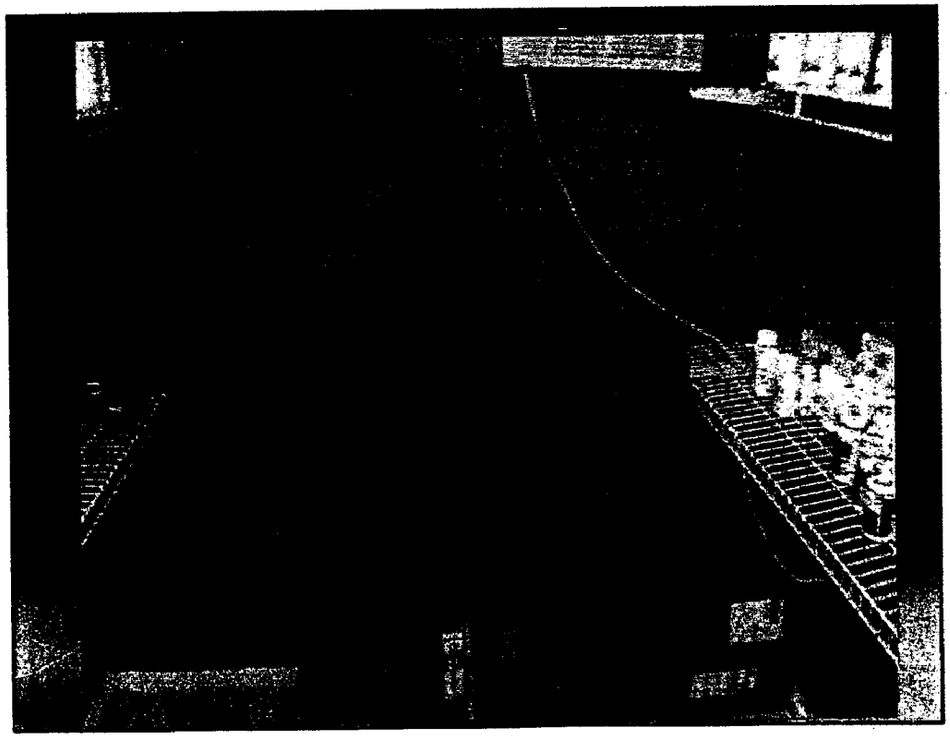
Example #1



Example #2

- Retail Pharmacy
  - Location of store
  - Only Hydrocodone and Alprazolam
  - Very large quantities
  - FedEx boxes for delivery

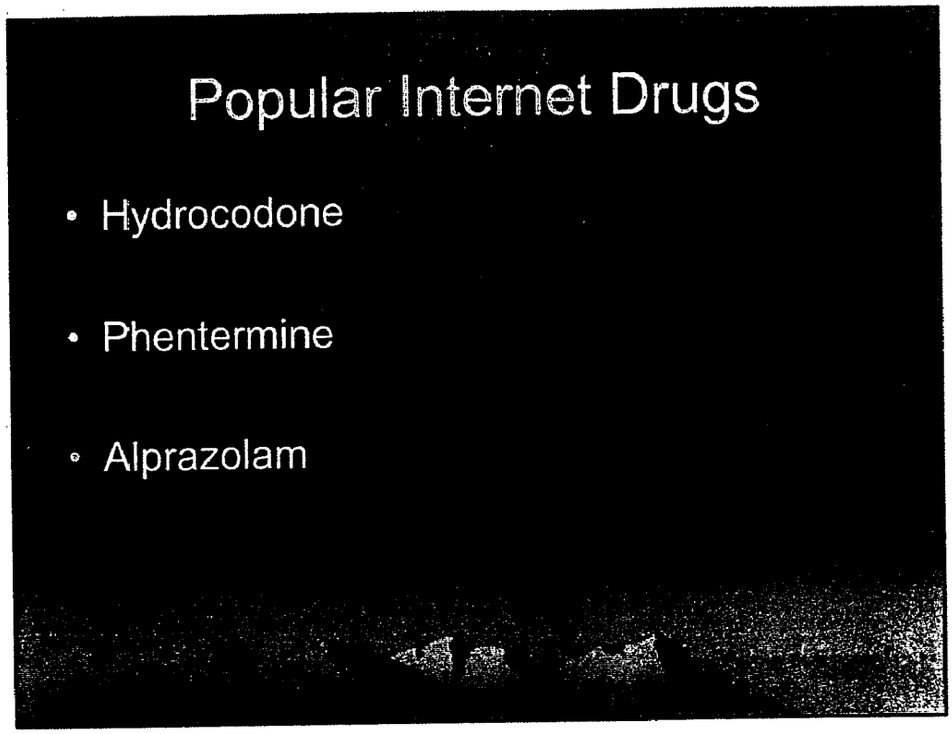


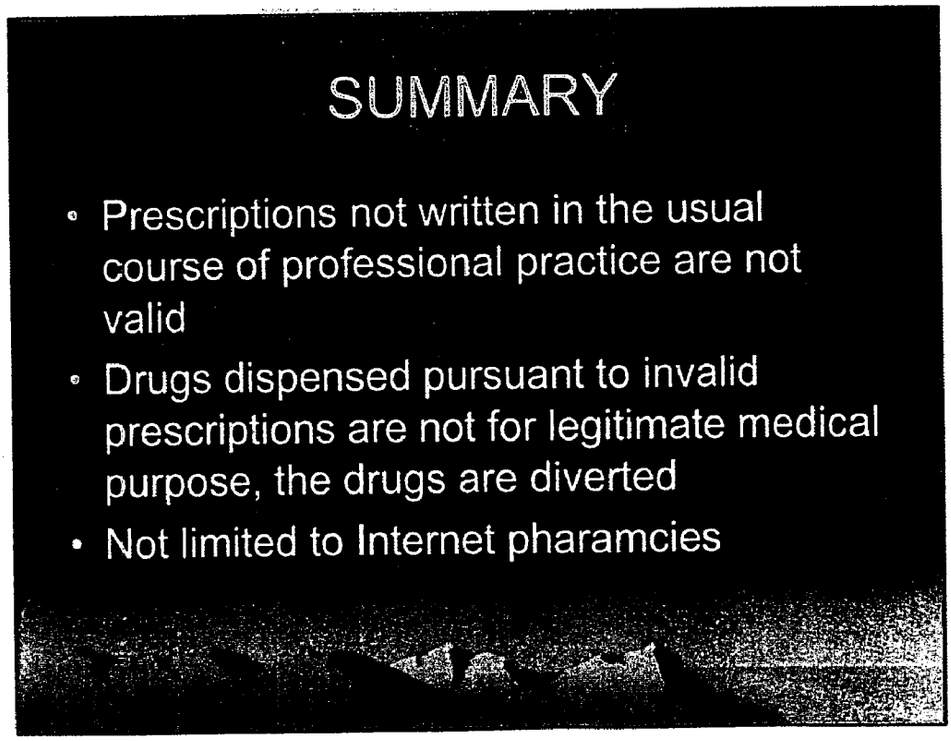


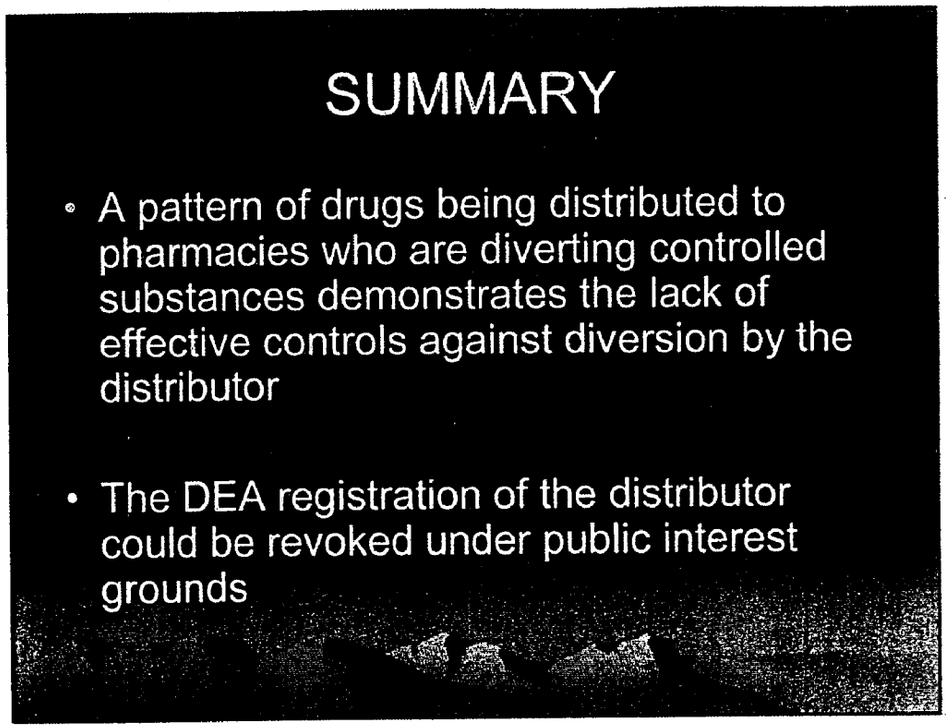
Example #3

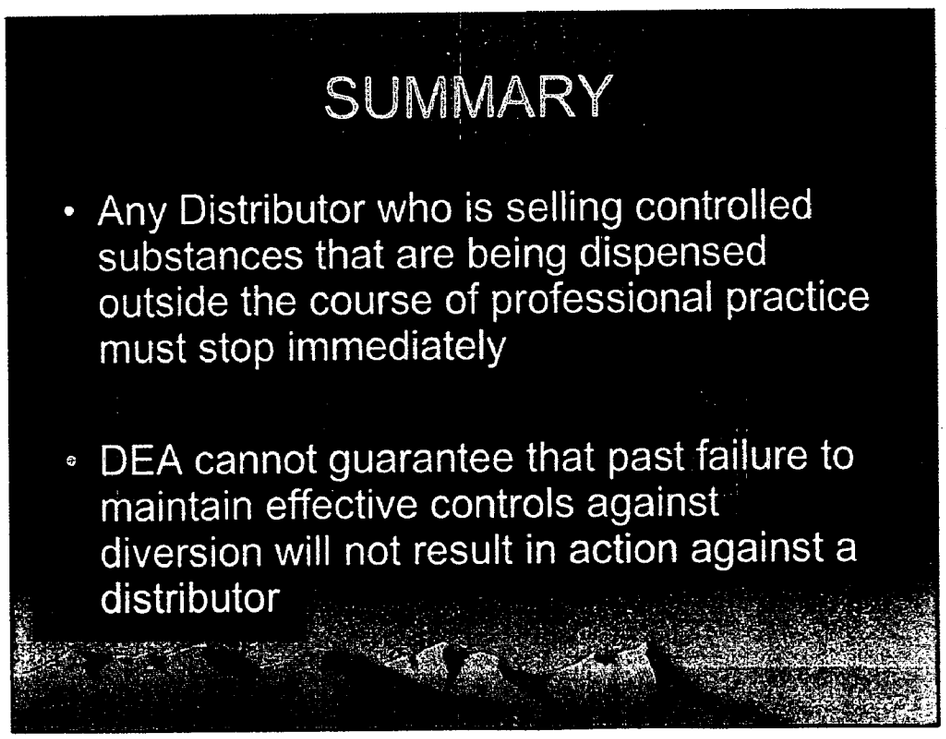
- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

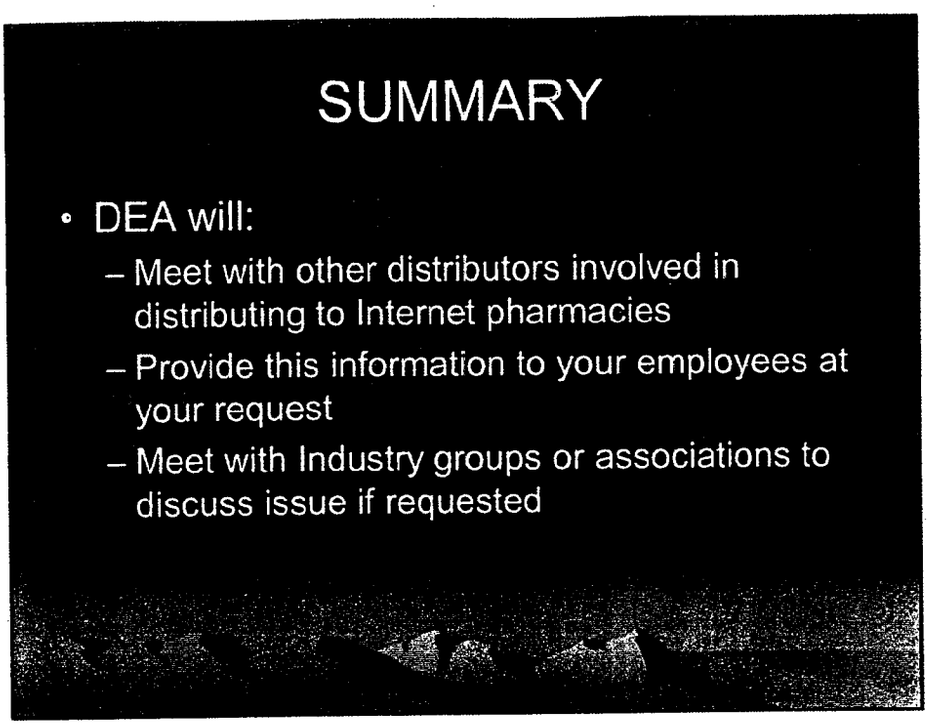
AN INTERNET PHARMACY











U.S. Code as of: 01/06/03

Section 823. Registration requirements

Related Res

Health Law

Department of J Human Se Directo

Department o Directo

Agriculture D

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent

with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting

research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or

detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) In any case in which the practitioner is not in a group practice, the total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number.

(iv) In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the

Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term ''group practice'' has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term ''qualifying physician'' means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this

paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug. (FOOTNOTE 1)

(FOOTNOTE 1) So in original. Probably should be ''combinations of drugs.''.

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on October 17, 2000, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that this paragraph should not remain in effect, this paragraph ceases to be in effect 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider -

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

Previous **[Notes]** **Next**

U.S. Supreme Court

DIRECT SALES CO. v. UNITED STATES, 319 U.S. 703 (1943)

319 U.S. 703

DIRECT SALES CO., Inc.,
v.
UNITED STATES.
No. 593.

Argued April 12, 1943.
Decided June 14, 1943.

[319 U.S. 703, 704] Mr. Wm. B. Mahoney, of Buffalo, N.Y., for petitioner.

Mr. Valentine Brookes, of Washington, D.C., for respondent.

Mr. Justice RUTLEDGE delivered the opinion of the Court.

Petitioner, a corporation, was convicted of conspiracy to violate the Harrison Narcotic Act. 1 It challenges the sufficiency of the evidence to sustain the conviction. Because of asserted conflict with United States v. Falcone, 311 U.S. 205, 61 S.Ct. 204, certiorari was granted.

Petitioner is a registered drug manufacturer and wholesaler. 2 It conducts a nationwide mail-order business from Buffalo, New York. The evidence relates chiefly to its transactions with one Dr. John V. Tate and his dealings with others. He was a registered physician, practicing in Calhoun Falls, South Carolina, a community of about 2000 persons. He dispensed illegally vast quantities of morphine sulphate purchased by mail from petitioner. The indictment charged petitioner, Dr. Tate, and three others, Black, Johnson and Foster, to and through whom Tate illegally distributed the drugs, with conspiring to violate [319 U.S. 703, 705] Sections 1 and 2 of the Act,3 over a period extending from 1933 to 1940. Foster was granted a severance, Black and Johnson pleaded guilty, and petitioner and Dr. Tate were convicted. Direct Sales alone appealed. The Circuit Court of Appeals affirmed. 131 F.2d 835.

The parties here are at odds concerning the effect of the Falcone decision as applied to the facts proved in this case. The salient facts are that Direct Sales sold morphine sulphate to Dr. Tate in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally. Not only so, but it actively stimulated Tate's purchases.

He was a small-town physician practicing in a rural section. All of his business with Direct Sales was done by mail. Through its catalogues petitioner first made [319 U.S. 703, 706] contact with him prior to 1933. Originally he purchased a variety of pharmaceuticals. But gradually the character of his purchases narrowed, so that during the last two years of the period alleged for the conspiracy he ordered almost nothing but morphine sulphate. At all times during the period he purchased the major portion of his morphine sulphate from petitioner. The orders were made regularly on his official order forms. The testimony shows the average physician in the United States does not require more than 400 one-quarter grain tablets annually for legitimate use. Although Tate's initial purchases in 1933 were smaller, they

gradually increased until, from November, 1937, to January, 1940, they amounted to 79,000 one-half grain tablets. In the last six months of 1939, petitioner's shipments to him averaged 5,000 to 6,000 half-grain tablets a month, enough as the Government points out to enable him to give 400 average doses every day.

These quantity sales were in line with the general mail-order character of petitioner's business. By printed catalogues circulated about three times a month, it solicits orders from retail druggists and physicians located for the most part in small towns throughout the country. Of annual sales of from $300,000 to $350,000 in the period 1936 to 1940, about fifteen per cent by revenue and two-and-a-half per cent by volume were in narcotics. he mail- order plan enabled petitioner to sell at prices considerably lower than were charged by its larger competitors, who maintained sales forces and traveling representatives. By offering fifty per cent discounts on narcotics, it 'pushed' quantity sales. Instead of listing narcotics, like morphine sulphate, in quantities not exceeding 100 tablets, as did many competitors, Direct Sales for some time listed them in 500, 1000 and 5000 tablet units. By this policy it attracted customers, including a dispropor- [319 U.S. 703, 707] tionately large group of physicians who had been convicted of violating the Harrison Act.

All this was not without warning, purpose or design. In 1936 the Bureau of Narcotics informed petitioner it was being used as a source of supply by convicted physicians. 4 The same agent also warned that the average physician would order no more than 200 to 400 quarter-grain tablets annually5 and requested it to eliminate the listing of 5000 lots. It did so, but continued the 1000 and 500 lot listings at attractive discounts. It filled no more orders from Tate for more than 1000 tablets, but continued to supply him for that amount at half-grain strength. On one occasion in 1939 he ordered on one form 1000 half and 100 quarter grains. Petitioner sent him the 1000 and advised him to reorder the 100 on a separate order form. It attached to this letter a sticker printed in red suggesting anticipation of future needs and taking advantage of discounts offered. Three days later Tate ordered 1000 more tablets, which petitioner sent out. In 1940, at the Bureau's suggestion, Direct Sales eliminated its fifty and ten per cent discounts. But on doing so it translated its discount into its net price.

Tate distributed the drugs to and through addicts and purveyors, including Johnson, Black and Foster. Although he purchased from petitioner at less than two dol- [319 U.S. 703, 708] lars, he sold at prices ranging from four to eight dollars per 100 half- grain tablets and purveyors from him charged addicts as much as $25 per hundred.

On this evidence, the Government insists the case is in different posture from that presented in United States v. Falcone. It urges that the effort there was to connect the respondents with a conspiracy between the distillers on the basis of the aiding and abetting statute. 6 The attempt failed because the Court held the evidence did not establish the respondents knew of the distillers' conspiracy. There was no attempt to link the supplier and the distiller in a conspiracy inter sese. But in this case that type of problem is presented. Direct Sales was tried, and its conviction has been sustained, according to the claim, on the theory it could be convicted only if it were found that it and Tate conspired together to subvert the order form provisions of the Harrison Act. As the brief puts the Government's view, 'Petitioner's guilt was not made to depend at all upon any guilt of Dr. Tate growing out of his relationship to defendants other than petitioner or upon whether these other defendants were linked with the Tate-Direct Sales conspiracy.'

On the other hand, petitioner asserts this case falls squarely within the facts and the ruling in the Falcone case. It insists there is no more to show conspiracy between itself and Tate than there was to show conspiracy between the respondent sellers and the purchasing distillers there. At most, it urges, there were only legal sales by itself to Dr. Tate, accompanied by knowledge he was distributing goods illegally. But this, it contends, cannot amount to conspiracy on its part with him, since in the Falcone case the respondents sold to the distillers, knowing they would use the goods in illegal distillation. [319 U.S. 703, 709] Petitioner obviously misconstrues the effect of the Falcone decision in one respect. This is

in regarding it as deciding that one who sells to another with knowledge that the buyer will use the article for an illegal purpose cannot, under any circumstances, be found guilty of conspiracy with the buyer to further his illegal end. The assumption seems to be that, under the ruling, so long as the seller does not know there is a conspiracy between the buyer and others, he cannot be guilty of conspiring with the buyer, to further the latter's illegal and known intended use, by selling goods to him.

The Falcone case creates no such sweeping insulation for sellers to known illicit users. That decision comes down merely to this, that one does not become a party to a conspiracy by aiding and abetting it, through sales of supplies or otherwise, unless he knows of the conspiracy; and the inference of such knowledge cannot be drawn merely from knowledge the buyer will use the goods illegally. The Government did not contend, in those circumstances, as the opinion points out, that there was a conspiracy between the buyer and the seller alone. It conceded that on the evidence neither the act of supplying itself nor the other proof was of such a character as imported an agreement or concert of action between the buyer and the seller amounting to conspiracy. This was true, notwithstanding some of the respondents could be taken to know their customers would use the purchased goods in illegal distillation.

The scope of the concession must be measured in the light of the evidence with reference to which it was made. This related to both the volume of the sales and to casual and unexplained meetings of some of the respondents with others who were convicted as conspirators. The Court found this evidence too vague and uncertain to support a finding the respondents knew of the distillers' conspiracy, [319 U.S. 703, 710] though not inadequate in some instances to sustain one that the seller knew the buyer would use the goods for illegal distilling. It must be taken also that the Government regarded the same evidence as insufficient to show the seller conspired directly with the buyer, by selling to him with knowledge of his intended illegal use.

Whether or not it was consistent in making this concession and in regarding the same evidence as sufficient to show that the sellers knew of and joined the buyers' distilling ring is not material. Nor need it be determined whether the Government conceded too much. We do not now undertaken to say what the Court was not asked and therefore declined to say in the Falcone case, namely, that the evidence presented in that case was sufficient to sustain a finding of conspiracy between the seller and the buyer inter sese. For, regardless of that, the facts proved in this case show much more than the evidence did there.

The commodities sold there were articles of free commerce, sugar, cans, etc. They were not restricted as to sale by order form, registration, or other requirements. When they left the seller's stock and passed to the purchaser's hands, they were not in themselves restricted commodities, incapable of further legal use except by compliance with rigid regulations, such as apply to morphine sulphate. The difference is like that between toy pistols or hunting rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the sam susceptibility to harmful and illegal use. Nor, by the same token, do all embody the same capacity, from their very nature, for giving the seller notice the buyer will use them unlawfully. Gangsters, not hunters or small boys, comprise the normal private market for machine guns. So drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade. [319 U.S. 703, 711] This difference is important for two purposes. One is for making certain that the seller knows the buyer's intended illegal use. The other is to show that by the sale he intends to further, promote and cooperate in it. This intent, when given effect by overt act, is the gist of conspiracy. While it is not identical with mere knowledge that another purposes unlawful action, it is not unrelated to such knowledge. Without the knowledge, the intent cannot exist. United States v. Falcone, supra. 7 Furthermore, to establish the intent, the evidence of knowledge must be clear, not equivocal. Ibid, This, because charges of conspiracy are not to be made out by piling inference upon inference, thus fashioning what, in that case, was called a dragnet to draw in all substantive crimes.

The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, arising from the latters' inherent capacity for harm and from the very fact they are restricted, makes a difference in the quantity of proof required to show knowledge that the buyer will utilize the article unlawfully. Additional facts, such as quantity sales, high pressure sales methods, abnormal increases in the size of the buyer's purchases, etc., which would be wholly innocuous or not more than ground for suspicion in relation to unrestricted goods, may furnish conclusive evidence, in respect to restricted articles, that the seller knows the buyer has an illegal object and enterprise. Knowledge, equivocal and uncertain as to one, becomes sure as to the other. So far as knowl- [319 U.S. 703, 712] edge is the foundation of intent, the latter thereby also becomes the more secure.

The difference in the commodities has a further bearing upon the existence and the proof of intent. There may be circumstances in which the evidence of knowledge is clear, yet the further step of finding the required intent cannot be taken. Concededly, not every instance of sale of restricted goods, harmful as are opiates, in which the seller knows the buyer intends to use them unlawfully, will support a charge of conspiracy. 8 But this is not to say that a seller of harmful restricted goods has license to sell in unlimited quantities, to stimulate such sales by all the high-pressure methods, legal if not always appropriate, in the sale of free commodities; and thereby bring about subversion of the other forms, which otherwise would protect him, and violation of the Act's other restrictions. Such a view would assume that the market for opiates may be developed as any other market. But that is not true. Mass advertising and bargain counter discounts are not appropriate to commodities so surrounded with restrictions. They do not create new legal demand and new classes of legitimare patrons, as they do for sugar, tobacco and other free commodities. Beyond narrow limits, the normal legal market for opiates is not capable of being extended by such methods. The primary effect is rather to create black markets for dope and to increase illegal demand and consumption. [319 U.S. 703, 713] When the evidence discloses such a system, working in prolonged cooperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise, there is no legal obstacle to finding that the supplier not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible. The step from knowledge to intent and agreement may be taken. There is more than suspicion, more than knowledge, acquiescence, carelessness, indifference, lack of concern. There is informed and interested cooperation, stimulation, instigation. And there is also a 'stake in the venture' which, even if it may not be essential, is not irrelevant to the question of conspiracy. 9 Petitioner's stake here was in making the profits which it knew could come only from its encouragement of Tate's illicit operations. In such a posture the case does not fall doubtfully outside either the shadowy border between lawful co-operation and criminal association or the no less elusive line which separates conspiracy from overlapping forms of criminal cooperation.

Unless, therefore, petitioner has been exempted arbitrarily by the statute's terms, the evidence clearly was sufficient to sustain its conviction for conspiring with Tate. Its position here comes down ultimately to the view alluded to above that the statute has, in fact, thus immunized its action. In effect this means the only restriction imposed upon it, apart from other provisions not now material, such as those affecting registration, was the requirement it should receive from purchasing physicians a signed order form for each sale. That done, in its view, its full duty to the law was fulfilled, it acquired a complete immunity, and what the physician had done [319 U.S. 703, 714] or might do with the drugs became of no further concern to itself. Such a view would legalize an express written agreement between a registered wholesaler and a physician for the former to supply him with all his requirements for drugs for both legal and illegal distribution, conditioned only upon his using the required order forms. The statute contains no such exemption in explicit terms. Nor was one implied. 10

This being true, it can make no difference the agreement was a tacit understanding, created by a long course of conduct and executed in the same way. 11 Not the form or manner in which the understanding is made, but the fact of its existene and the further one of making it effective by overt conduct are the crucial matters. The proof, by the very nature of the crime, must be circumstantial12 and therefore

inferential to an extent varying with the conditions under which the crime may be committed. But this does not mean either that the evidence may be equivocal or that petitioner is exempt from its effects when it is not so, merely because in the absence of excesses such as were committed and in other circumstances the order form would have given it protection. It follows the mere fact that none of petitioner's representatives ever met Dr. Tate face to face or held personal communion with him is immaterial. Conspiracies, in short, can be committed by mail and by mail-order houses. This is true, n twithstanding the overt acts consist solely of sales, which but for their volume, frequency and prolonged [319 U.S. 703, 715] repetition, coupled with the seller's unlawful intent to further the buyer's project, would be wholly lawful transactions.

Accordingly, the judgment is

Affirmed.

Footnotes

[Footnote 1] The conspiracy statute, R.S. 5440, as amended, 18 U.S.C. 88, provides:

> 'If two or more persons conspire either to commit any offense against the United States, or to defraud the United States in any manner or for any purpose, and one or more of such parties do any act to effect the object of the conspiracy, each of the parties to such conspiracy shall be fined not more than $10,000, or imprisoned not more than two years, or both.'

The pertinent provisions of the Harrison Act are set out in note 3, infra.

[Footnote 2] 38 Stat. 785, as amended, 26 U.S.C. 3220, 3221.

[Footnote 3] 38 Stat. 785, as amended, 26 U.S.C. 2553, 2554. The indictment charged the conspiracy's object was to violate those portions of the Act (as amended) which provide:

> 'It shall be unlawful for any person required to register under the provisions of this part or section 2551(a) to import, manufacture, produce, compound, sell, deal in, dispense, distribute, administer, or give away any of the aforesaid drugs without having registered and paid the special tax as imposed by this part, or section 2551(a).' 26 U.S.C. 3224.
>
> 'It shall be unlawful for any person to purchase, sell, dispense, or distribute any of the drugs mentioned in section 2550(a) except in the original stamped package or from the original stamped package ....' 26 U. S.C. 2553.
>
> 'It shall be unlawful for any person to sell, barter, exchange, or give away any of the drugs mentioned in section 2550(a) except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Secretary.' 26 U.S.C. 2554(a).
>
> 'It shall be unlawful for any person to obtain by means of said order forms any of the aforesaid drugs for any purpose other than the use, sale, or distribution thereof by him in the conduct of a lawful business in said drugs or in the legitimate practice of his profession.' 26 U.S.C. 2554(g).

[Footnote 4] Thus, although there were more than 1350 wholesale drug dealers in the United States from whom physicians might order narcotics (Traffic in Opium and Other Dangerous Drugs for the Year Ended December 31, 1941, United States Treasury, Bureau of Narcotics), about 27% of the 204 doctors convicted were petitioner's customers.

[Footnote 5] Testimony in the record establishes that the practice in the profession is to give one-eighth or one-fourth grain doses, and only rarely one-half grain doses. Cf. United States v. Behrman, 258 U.S. 280, 289 , 42 S.Ct. 303, 305. Furthermore, there was expert testimony to the effect that codein may be, and preferably is, used for the same medical purposes as morphine sulphate. During the period from 1934 to 1940, however, the record does not show that Tate ever ordered codein from petitioner.

[Footnote 6] R.S. 5323, 18 U.S.C. 550.

[Footnote 7] Although this principle was there applied to aiding and abetting a conspiracy among others, it has at least equal force in a situation where the charge is conspiring with another to further his unlawful conduct, without reference to any conspiracy between him and third persons.

[Footnote 8] This may be true, for instance, of single or casual transactions, not amounting to a course of business, regular, sustained and prolonged, and involving nothing more on the seller's part than indifference to the buyer's illegal purpose and passive acquiescence in his desire to purchase, for whatever end. A considerable degree of carelessness coupled with casual transactions is tolerable outside the boundary of conspiracy. There may be also a fairly broad latitude of immunity for a more continuous course of sales, made either with strong suspicion of the buyer's wrongful use or with knowledge, but without stimulation or active incitement to purchase.

[Footnote 9] Cf. United States v. Falcone, 2 Cir., 109 F.2d 579, 581; and compare Backun v. United States, 4 Cir., 112 F.2d 635, 637; United States v. Harrison, 3 Cir., 121 F.2d 930, 933; United States v. Pecoraro, 2 Cir., 115 F.2d 245, 246.

[Footnote 10] Cf. Gebardi v. United States, 287 U.S. 112 , 53 S.Ct. 35, 84 A.L.R. 370; see also 81 U. of Pa.L.Rev. 474.

[Footnote 11] Glasser v. United States, 315 U.S. 60, 80 , 62 S.Ct. 457, 469; United States v. Manton, 107 F.2d 834, 839; United States v. Harrison, 3 Cir., 121 F.2d 930, 934; Eastern States Retail Lumber Dealers' Ass'n v. United States, 234 U.S. 600 , 34 S.Ct. 951, L.R.A. 1915A, 788; Interstate Circuit, Inc., v. United States, 306 U.S. 208 , 59 S. Ct. 467.

[Footnote 12] Ibid.

Registrant Actions - 2004

FR Doc 04-24235 [Federal Register: October 29, 2004 (Volume 69, Number 209)] [Notices] [Page 63178-63182] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr29oc04-105]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

EZRX, LLC Revocation of Registration

On May 17, 2004, the Deputy Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause and Immediate Suspension of Registration to EXRX, LLC (EZRX) of Union, New Jersey. EZRX was notified of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BE8488783, as a retail pharmacy, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for reason that its continued registration would be inconsistent with the public interest. EZRX was further notified that its DEA registration was immediately suspended as an imminent danger to the public health and safety pursuant to 21 U.S.C. 824(d).

The Order to Show Cause and Immediate Suspension alleged in sum, that EZRX was engaged in illegally dispensing controlled substances as part of a scheme in which controlled substances were dispensed by EZRX based on Internet orders placed by customers and approved by associated physicians, based solely on their review of Internet questionnaires and without personal contact, examination or bona fide physician/patient relationships. Such prescriptions were not issued ``in the usual course of professional treatment'' and violated 21 CFR 1306.04 and 21 U.S.C. 841(a). This action was part of a nationwide enforcement operation by DEA titled Operation Pharmnet, which targeted online suppliers of prescription drugs, including owners, operators, pharmacists and doctors, who have illegally and unethically been marketing controlled substances via the Internet.

According to the investigative file on May 26, 2004, the Order to Show Cause and Immediate Suspension of Registration was personally served by Special Agents and Diversion Investigators of the DEA at EZRX's registered premises in Union, New Jersey. More than thirty days have passed since the Order to Show Cause

[[Page 63179]]

and Immediate Suspension of Registration was served on EZRX and DEA has not received a request for

hearing or any other reply from EZRX or anyone purporting to represent it in this matter.

Therefore, the Deputy Administrator of DEA, finding that (1) thirty days having passed since the delivery of the Order to Show Cause and Immediate Suspension of Registration to EZRX, and (2) no request for hearing having been received, concludes that EZRX is deemed to have waived its hearing right. See David W. Linder, 67 FR 12,579 (2002). After considering material from the investigative file in this matter, the Deputy Administrator now enters her final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds EZRX is currently registered with DEA as a retail pharmacy under DEA Registration, BE8488783 to dispense Schedule II through V Controlled Substances. That registration expires on August 31, 2006. The owners of EZRX are Frank C. Hernandez and his wife, Amada Hernandez.

In 2003, the DEA Miami Field Division initiated regulatory investigations of C&H Wholesale, Inc. (C&H) and Lifeline Pharmacy, Inc. (Lifeline). C&H was registered with DEA as a distributor of Schedule II through V controlled substances and Lifeline was registered as a retail pharmacy of the same substances. Both companies are owned by Mr. and Mrs. Hernandez and the registered premises they occupy are physically connected and share floor space with the Hernandez' non-drug businesses.

During the regulatory examination of C&H, it was discovered that C&H was distributing controlled substances almost exclusively to South Florida pharmacies, including Lifeline, which were filling Internet controlled substance prescriptions. The majority of distributions were for Schedule III and IV controlled substance weight loss medications including, but not limited to substantial quantities of phentermine, phendimetrazine tartrate, Dexedrine and tenuate.

On October 10, 2003, as a result of investigative findings that C&H and Lifeline were facilitating and dispensing controlled substances by virtue of prescriptions issued not for legitimate medical purposes and not in the usual course of professional medical practice, the then- Acting Deputy Administrator issued orders to show cause to C&H and Lifeline and immediately suspended their registrations on grounds that the posed an immediate threat to the public health and safety.

Subsequent investigation by Miami DEA investigators revealed that on August 21, 2003, the same day a federal search warrant was being executed on Lifeline's Florida premises, Mr. Hernandez filed a new application for registration on behalf of EZRX, as a retail pharmacy in New Jersey. That application was inadvertently routinely processed in New Jersey while the Miami investigation was still in process and it was approved on September 9, 2003. Later, in the course of document review, DEA Miami investigators found paperwork indicating Mr. and Mrs. Hernandez were the owners of EZRX and that two Florida employees, Mr. Hernandez' nephew and wife, were also key employees of the New Jersey retail pharmacy.

On November 6, 2003, DEA Miami investigators made an undercover buy from a Florida-based website. Using a fictitious name and an undercover Internet e-mail account and computer, investigators placed an order for Bontril, a Schedule IV controlled substance weight loss medication. After filling out a medical questionnaire on the website and sending a money order to an affiliated company, E.V.A. Global, Inc., a package was received at the undercover address via Federal Express. It was shipped by EZRX on November 11, 2003, from its registered address and contained 89 Bontril SR 105mg capsules. The prescription label indicated it had been dispensed by EZRX and the issuing physician was an individual, later identified as a DEA registrant, who had prescribed controlled substances during similar undercover purchases made through Lifeline. There was no contact between the prescribing physician and the undercover investigator, other than transmission of the Internet questionnaire.

Another physician involved with Internet prescribing thorough E.V.A. Global, Inc. was interviewed by investigators and described the process. He would access a web site provided him by E.V.A. Global, Inc., where customers' medical questionnaires would be posted. The physician would access the questionnaires one at a time, review the questionnaire and either approve or deny the prescription request. He did not

have the ability to suggest an alternative drug or an alternate amount and there was never any contact between the physician and either the ``patient'' or the dispensing pharmacy.

It was determined that from September through November 2003, EZRX ordered in excess of 300,000 dosage units of Schedule III and IV controlled substances, including the controlled substances commonly sold through websites affiliated with E.V.A. Global, Inc., to include phentermine, Ionamin, Meridia, Didrex, phendimetrazine tartrate and Ambien.

The Controlled Substances Act (CSA) establishes a ``closed system'' of distribution that regulates the movement of controlled substance prescription medications from importation or manufacture through their delivery to the ultimate user patient via the dispensing, administering or prescribing, pursuant to the lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows: ``A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).

Prescriptions issued not in the ``usual course of professional treatment'' are not ``prescriptions'' for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's controlled substances provisions.

In United States v. Moore, 423 U.S. 122 (1975), the Supreme Court held that, ``Implicit in the registration of a physician is the understanding that he is authorized only to act `as a physician'.'' Id., at 141. In Moore the court implicitly approved a jury instruction that acting ``as a physician'' is acting ``in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.'' Id., at 138-139; see, United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986). Responsible professional organizations have issued guidance in this area. The American Medical Association's guidance for physicians on the appropriate use of the Internet in prescribing medication (H-120.949 Guidance for Physicians on Internet Prescribing) states:

``Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:

> i. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying

[[Page 63180]]

> conditions and/or contraindications to the treatment recommended/ provided;
>
> ii. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
>
> iii. As appropriate, follow up with the patient to assess the therapeutic outcome;
>
> iv. Maintain a contemporaneous medical record that is readily available to the patient and, subject to the patient's consent, to his or her other health care professionals; and
>
> v. Include the electronic prescription information as part of the patient medical record.''

In April 2000, the Federation of State Medical Boards adopted Model Guidelines for the Appropriate use of the Internet in Medical Practice, which states, in pertinent part, that:

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-

face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

The CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's ``corresponding responsibility'' regarding the proper dispensing of controlled substances is explicitly described in 21 CFR 1306.04(a). It provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

In an April 21, 2001, policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, inter alia, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship required that the patient has a medical complaint, a medical history be taken, a physical examination performed, and some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed. The policy statement specifically explained that the completion of ``a questionnaire that is then review by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship * * * '' Id., at 21,182-21,183.

Rogue Internet Pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory and incomplete online questionnaire or perfunctory telephone ``consult'' with a doctor, who usually has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. The Food and Drug Administration (FDA) considers the questionnaire, in lieu of face-to- face interaction, to be a practice that undermines safeguards of direct medical supervision and amounts to substandard medical care. See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (http://fda.gov/oc/buyonline/default.htm).

The National Association of Boards of Pharmacy considers internet pharmacies to be suspect if:

They dispense prescription medications without requiring the consumer to mail in a prescription, and if they dispense prescription medications and do not contact the patient's prescriber to obtain a valid verbal prescription. Further, online pharmacies are suspect if they dispense prescription medications solely based upon the consumer completing an online questionnaire without the consumer having a pre-existing relationship with a prescriber and the benefit of an in-person physical examination. State boards of pharmacy, boards of medicine, the FDA, as well as the AMA, condemn this practice and consider it to be unprofessional.

See, National Association of Boards of Pharmacy, VIIPS Program, Most Frequently Asked Questions (http://www.nabp.net/vipps/consumer/faq.asp).

Rogue Internet pharmacies often use persons with limited or no knowledge of medications and standard pharmacy practices to fill prescriptions, do not advertise the availability of pharmacists for medication consultation, and focus on select medications, usually lifestyle, obesity and pain medications. Rogue Internet pharmacies generally do not protect the integrity of original faxed prescriptions by requiring that they be received directly from the prescriber (not the patient) and do not verify the authenticity of suspect prescriptions.

When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice. The

FDA has stated:

We know that adverse events are under-reported and we know from history that tolerating the sale of unproven, fraudulent, or adulterated drugs results in harm to the public health. It is reasonable to expect that the illegal sales of drugs over the Internet and the number of resulting injuries will increase as sales on the Internet grow. Without clear and effective law enforcement, violators will have no reason to stop their illegal practices. Unless we begin to act now, unlawful conduct and the resulting harm to consumers most likely will increase.

See U.S. Food and Drug Administration, Buying Medicines and Medical Products Online, General FAQs (http://fda.gov/oc/buyonline/default.htm).

Pursuant to 21 U.S.C. 823(f) and 824(a)(4), the Deputy Administrator may revoke a DEA Certificate of Registration and deny any pending application for renewal of such registration, if she determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered in determining the public interest:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable state, federal, or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health or safety.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration denied. See Henry J. Schwartz, Jr., M.D., 54 FR 16,422 (1989).

In this case, the Deputy Administrator finds factors two, four and five relevant to a determination of whether EZRX's continued registration remains consistent with the public interest.

With regard to factor one, the recommendation of the appropriate state licensing board or professional disciplinary authority, there is no evidence in the investigative file that EZRX has been the subject of a state disciplinary proceeding, nor is there

[[Page 63181]]

evidence demonstrating that its state pharmacy license or state controlled substance authority are currently restricted in any form. Nevertheless, state licensure is a necessary, but not sufficient condition for registration, and therefore, this factor is not dispositive. See e.g., Wesley G. Harline, M.D., 65 FR 5,665-01 (2000); James C. LaJevic, D.M.D., 64 FR 55,962 (1999).

With regard to factors two and four, the Deputy Administrator finds that the primary conduct at issue in this proceeding (i.e., the unlawful dispensing of controlled substance prescriptions for use by Internet customers) relates to both EZRX's and its owners' experience in dispensing controlled substances, as well as its compliance with applicable state, federal, or local laws relating to controlled substances. DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. See Plaza Pharmacy, 53 FR 36,910 (1988)

A DEA registration authorizes a physician to prescribe or dispense controlled substances only within the usual course of his or her professional practice. For a prescription to have been issued within the course of a practitioner's professional practice, it must have been written for a legitimate medical purpose within the context of a valid physician-patient relationship. See Mark Wade, M.D., 69 FR 7,018 (2004). 51,600 (1998).

Legally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription. See Floyd A Santner, M.D., 55 FR 37,581 (1990).

Factors two and four are relevant to EZRX's dispensing of Internet prescribed controlled substances. The Deputy Administrator concludes from a review of the record that the physicians issuing these prescriptions did not establish valid physician-patient relationships with Internet customers to whom they prescribed controlled substances. DEA has previously found that prescriptions issued through a pharmacy Internet Web site are not considered as having been issued in the usual course of medical practice, in violation of 21 CFR 1306.04 and has revoked the DEA registrations of several physicians for participating in Internet prescribing schemes similar to or identical to that of EZRX. See, Marvin L. Gibbs, Jr., M.D., 69 FR 11,658 (2004); Mark Wade, M.D., supra, 69 FR 7,018; Ernesto A. Cantu, M.D., 69 FR 7,104-02 (2004); Rick Joe Nelson, M.D., 66 FR 30,752 (2001).

Similarly, in the past few years, DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill their corresponding responsibility in Internet prescribing operations, similar to those of EZRX and its principals and their affiliated companies. See Prescriptiononline.com, 69 FR 5,583 (2004); Pill Box Pharmacy (surrendered DEA registration as part of owner's and pharmacy's guilty plea to 21 U.S.C. 841(a)(1) violation); Friendly Pharmacy (pharmacist pled guilty and owner convicted at trial, of violating 21 U.S.C. 841(a). Indeed, C&H and Lifeline, the predecessor Internet pharmacy entities owned by EZRX's principals, were both subjects of orders to show cause with immediate suspensions and both companies surrendered their DEA Certificates of Registration.

In the instant case, physicians associated with the Internet operation authorized prescriptions for controlled substances without the benefit of face-to-face physician-patient contact, physical exam or medical test. There is no information in the investigative file demonstrating that the issuing physicians even took the time corroborate responses to questionnaires that were submitted by EZRX's customers. Here, it is clear that the issuance of controlled substance prescriptions to persons whom the prescribing physician has not established a valid physician-patient relationship is a radical departure from the normal course of professional practice and that EZRX knowingly participating in this scheme.

With regard to factor three, applicant's conviction record under federal or state laws relating to the dispensing of controlled substances, the record does not reflect that EZRX or its principals have been convicted of a felony related to controlled substances.

Regarding factor five, such other conduct which may threaten the public health or safety, the Deputy Administrator finds this factor relevant to EZRX's continued dispensing to Internet customers after issuance of policy statements designed to assist licensed practitioners and pharmacists in the proper prescribing and dispensing of dangerous controlled drugs.

Factor five is also relevant to EZRX's continued Internet prescribing after C&H and Lifeline, both owned by the principals of EZRX, were served with Orders to Show Cause and for Immediate Suspensions in October 2003. These entities sought an order in United States District Court seeking to restrain DEA from imposing the immediate suspensions of their registrations. After the District Court held hearings to make a threshold determination that DEA had some basis to back up its allegations regarding the Internet prescribing activities of C&H and Lifeline, the Court upheld the immediate suspensions by DEA, finding ``there is not a substantial likelihood that C&H and Lifeline will prevail on the merits." It further stated, ``the danger of the public obtaining controlled substances outweighs the threatened injury to C&H and Lifeline. Granting the preliminary injunction would affect the public interest, again putting the public in danger of obtaining controlled substances." See C&H Wholesale, Inc. and Lifeline Pharmacy, Inc., CIV 03-61910 (S.D. Fla., October 23, 2003). Nevertheless after the District Court's Order, EZRX continued this practice and dispensed the controlled substance ordered over the Internet by undercover agents on November 6, 2003.

Similarly, factor five is relevant to Mr. Hernandez' timing in applying for EZRX's DEA registration on August 21, 2003. This is the date a federal search warrant was executed on Lifeline, his Florida pharmacy and

further suggests the New Jersey operation was established by Mr. Hernandez to continue Internet dispensing as a back up to his Florida operations.

The Deputy Administrator has previously expressed her deep concern about the increased risk of diversion which accompanies Internet controlled substance transactions. Given the nascent practice of cyber-distribution of controlled drugs to faceless individuals, where interaction between individuals is limited to information on a computer screen or credit card, it is virtually impossible to insure that these highly addictive, and sometimes dangerous products will reach the intended recipient, and if so, whether the person purchasing these products has an actual need for them. The ramifications of obtaining dangerous and highly addictive drugs with the ease of logging on to a computer and the use of a credit card are disturbing and immense, particularly when one considers the growing problem of the abuse of prescription drugs in the United States. See, Mark Wade, M.D., supra, 69 FR 7,018.

The Deputy Administrator has also previously found that in a 2001 report, the National Clearinghouse for Alcohol and Drug Information estimated that 4 million Americans ages 12 and older had acknowledged misusing

[[Page 63182]]

prescription drugs. That accounts for 2% to 4% of the populations--a rate of abuse that has quadrupled since 1980. Prescription drug abuse-- typically of painkillers, sedatives and mood-altering drugs--accounts for one-third of all illicit drug use in the United States. See Mark Wade, M.D., supra, 69 FR 7,018.

The Deputy Administrator finds that with respect to Internet transactions involving controlled substances, the horrific untold stories of drug abuse, addiction and treatment are the unintended, but foreseeable consequence of providing highly addictive drugs to the public without oversight. The closed system of distribution, brought about by the enactment of the Controlled Substances Act, is completely compromised when individuals can easily acquire controlled substances without regard to age or health status. Such lack of oversight describes EZRX, its principals, their associated companies and affiliated physician's practice of issuing prescriptions for and distributing controlled substances to indistinct Internet customers. Such conduct contributes to the abuse of controlled substances by EZRX's customers and is relevant under factor five and further supports revocation of its DEA Certificate of Registration.

It appears that EZRX and its principals, motivated purely by profit and in pursuit of financial gain, have demonstrated a cavalier disregard for controlled substance laws and regulations and a disturbing indifference to the health and safety of customers who purchased dangerous drugs through the Internet. Such demonstrated lack of character and adherence to the responsibilities inherent in a DEA registration show in no uncertain terms that EZRX's continued registration with DEA would be inconsistent with the public interest.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration BE8488783, previously issued to EZRX, LLC, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effective November 29, 2004.

Dated: September 29, 2004.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 04-24235 Filed 10-28-04; 8:45 am]

BILLING CODE 4410-09-M

Back to Top

Registrant Actions - 2004

FR Doc 04-23715 [Federal Register: October 22, 2004 (Volume 69, Number 204)] [Notices] [Page 62093-62095] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr22oc04-112]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

ocket No. 04-01]

RX Network of South Florida, LLC Revocation of Registration

On October 10, 2003, the then-Acting Deputy Administrator of the Drug Enforcement Administration (DEA),

[[Page 62094]]

issued an Order to Show Cause and Immediate Suspension of Registration to RX Network of South Florida, LLC (Respondent), notifying it of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, BR7139238, as a retail pharmacy, and deny any pending applications for renewal or modification of registration pursuant to 21 U.S.C. 823(f) and 824(a)(4), for reason that Respondent's continued registration would be inconsistent with the public interest.

The Order to Show Cause and Immediate Suspension of Registration further informed Respondent of the suspension of its DEA Certificate of Registration, as an imminent danger to the public health or safety pursuant to 21 U.S.C. 824(d). The Order to Show Cause and Immediate Suspension of Registration alleged in relevant part, that Respondent, owned and operated by Vincent Chhabra, Sabrina Faruqui and Carleta Carolina, dispensed over 19,300,000 various controlled substances through orders of customers who had accessed an Internet Web site set up by Respondent. Customers of Respondent would complete a questionnaire set up on the Web site, which solicited ormation about the customer, including the type of medication desired. After the customer's credit card was processed, the questionnaire was forwarded to one of several "staff" physicians who then issued prescriptions for the controlled substances being ordered. The prescriptions were then sent electronically to Respondent, which then dispensed the controlled substances to customers through the mail. The "staff" physicians, as well as Respondent's customers, were located in various states

throughout the United States and the physicians had no interaction with customers before prescribing the controlled substances.

The Order to Show Cause and Immediate Suspension of Registration also alleged that on April 21, 2001, DEA issued a policy statement, Dispensing and Purchasing Controlled Substances over the Internet, 66 FR 21,181 (2001). The policy statement delineated certain circumstances under the which DEA deems prescribing over the Internet to be unlawful, including, inter alia, the circumstance when a controlled substance is issued or dispensed without a bona fide doctor/patient relationship. The policy further explained that completed questionnaires, later reviewed by a doctor hired by the Internet pharmacy "could not be considered the basis of a doctor/patient relationship." Id., at 21,182-21,183. In further support of DEA policy, the Order to Show Cause and Immediate Suspension of Registration cited the final order revoking the DEA registration of a practitioner who had participated in an Internet pharmacy scheme similar to that of Respondent. See Rick Joe Nelson, M.D. 66 FR 30,752 (2001).

The Order to Show Cause and Immediate Suspension of Registration further referenced correspondence during November 2002 and February 2003 between the United States Department of Justice and the then- attorney of Vincent Chhabar. In those letters, Mr. Chhabra's attorney was reminded that his client had been notified of the foregoing DEA policy and requested to shut down its Internet pharmacy operation. The Order to Show Cause and Immediate Suspension of Registration further referenced an order of emergency suspension issued by the Florida Department of Health (the Department) against Respondent on May 30, 2002, as well as administrative complaints issued by the Department's Pharmacy Board against Respondent and one of its pharmacists. While both actions stemmed from allegations that Respondent operated an Internet pharmacy, the Order to Show Cause and Immediate Suspension of Registration referenced the Pharmacy Board's March 31, 2003, assessment of a $48,000 fine as the only sanction.

The Order to Show Cause and Immediate Suspension of Registration further alleged that on seven separated occasions during September and October 2003, DEA diversion investigators and agents from the United States Food and Drug Administration conducted a series of undercover operations with the objective of obtaining controlled substances from Respondent through its Internet operation. The operation resulted in law enforcement officers receiving quantities of Bontril (a Schedule III controlled substance) and phentermine (a Schedule IV controlled substance) from Respondent after filling out Internet questionnaires with fictitious names and fictitious weights. The law enforcement officers had no contact with the prescribing physicians, who issued prescriptions from locations in Florida, Missouri and Pennsylvania. However, there were no allegations in the Order to Show Cause and Immediate Suspension of Registration addressing the status of Respondent's authorization to handle controlled substances in the State of Florida.

By letter dated November 3, 2003, Respondent, through counsel, requested a hearing in this matter. The request included various arguments challenging the basis for the Order to Show Cause and Immediate Suspension of Registration. On November 10, 2003, Presiding Administrative Law Judge Mary Ellen Bittner (Judge Bittner) issued an Order for Prehearing Statements.

On November 21, 2003, in lieu of a prehearing statement, counsel for DEA filed Government's Motion for Summary Judgment and Motion to Stay the Filing of Prehearing Statements. In support of its motions, the Government referenced a letter dated November 20, 2003, in which Respondent's counsel had notified the Florida Board of Pharmacy of the following: "Without the ability to dispense controlled substance[s], a crucial element of operating a pharmacy, [Respondent] can no longer remain viable, and must relinquish its pharmacy permit." According to the Government, the letter indicated Respondent no longer had a pharmacy license in the State of Florida and, as a result, further proceedings in the matter were not required. Attached to the Government's motion was the

aforementioned letter from Respondent's counsel to the Florida Board of Pharmacy. In response to the Government's motion, Respondent argued in relevant part, that the Order to Show Cause and Immediate Suspension of Registration had not alleged that it did not have a current state pharmacy license. Respondent further argued that its lack of such a license now rendered these proceedings "legally moot" and that the Administrative Law Judge should deny the Government's Motion for Summary Disposition and issue an order dismissing the case as moot.

On December 17, 2003, Judge Bittner issued her Opinion and Recommended Decision of the Administrative Law Judge (Opinion and Recommended Decision). As part of her recommended ruling, Judge Bittner rejected Respondent's contentions concerning the Government's failure to initially allege lack of state authority, holding the relevant question was Respondent's status to handle controlled substances at the time of the Opinion and Recommended Decision, not at what stage of the proceedings that status may have changed. She further noted Respondent had never surrendered its DEA Certificate of Registration and that the surrender of its state pharmacy license did not render this proceeding moot. Judge Bittner granted the Government's Motion for Summary Disposition, finding Respondent lacked authorization to handle controlled

[[Page 62095]]

substances in Florida, the jurisdiction in which it is registered with DEA. In granting the Government's motion, Judge Bittner further recommended that Respondent's DEA registration be revoked and any pending applications be denied. According to the letter transmitting this matter to the Deputy Administrator, no exceptions were filed by either party to the Opinion and Recommended Decision.

The Deputy Administrator has considered the record in its entirety and pursuant to 21 CFR 1316.67, hereby issues her final order based upon the findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the Opinion and Recommenced Decision of the Administrative Law Judge.

The Deputy Administrator finds that Respondent currently possesses DEA Certificate of Registration RB7139238 and is registered to handle controlled substances in Florida as a retail pharmacy. The Deputy Administrator's review of the November 20, 2003, letter from Respondent's counsel to the Florida Board of Pharmacy reveals that after receiving the order of immediate suspension of its DEA registration, Respondent surrendered its pharmacy permit to the Board of Pharmacy. It appears from this action that Respondent surrendered its authority to handle controlled substances in Florida and, as a result, lacks a necessary prerequisite for DEA registration. There is no evidence before the Deputy Administrator that Respondent's pharmacy permit has been returned or reinstated or that Respondent is currently licensed in Florida as a retail pharmacy. Accordingly, it is reasonable to infer that Respondent is without authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See Prescriptionline.com, 69 FR 5583 (2004); Graham Travers Schuler, M.D., 65 FR 50,570 (2000); Wingfield Drugs, Inc., 52 FR 27,070 (1987). The agency has also maintained this standard in matters involving the immediate suspension of a DEA Certificate of Registration under 21 U.S.C. 824(d). See Chemical Dependence Associates of Houston, 58 FR 37505 (1993).

Here, Respondent is currently not licensed to handle controlled substances in Florida, the state where it maintains its registration with DEA. Therefore, Respondent is not entitled to maintain that registration.

Because Respondent is not entitled to a DEA registration in Florida due to its lack of state authorization to handle controlled substances, the Deputy Administrator concludes it is unnecessary to address whether Respondent's registration should be revoked based upon the public interest grounds asserted in the Order to Show Cause and Immediate Suspension of Registration. See Deanwood Pharmacy, 68 FR 41662 (2003); Nathaniel-Aikens-Afful, M.D., 62 FR 16871 (1997); Greenbelt Professional Pharmacy, 57 FR 55000 (1992).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in her by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, BR7139238, issued to RX Network of South Florida, LLC, be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective November 22, 2004.

Dated: October 5, 2004.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 04-23715 Filed 10-21-04; 8:45 am]

BILLING CODE 4410-09-M

Back to Top